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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,069	11/27/2001	Cynthia C. Bamdad	M1015.70071US	1136

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,069	BAMDAD ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-224* is/are pending in the application.

4a) Of the above claim(s) *4-224* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group 1, claims 1-3 in the reply filed on August 15, 2006 is acknowledged. The traversal is on the ground(s) that the claimed invention which, directed to a series of compositions, method, kits, articles and species associated with the diagnosis and/or treatment of proliferation (cancer), is closely related to form a single invention. Searching of all of 224 pending claims would not put a serious burden on the examiner. This is not found persuasive because each of different proliferative marker proteins require separate search both in the U.S. patent system and non-patent literature system. This will put a serious search burden on the examiner. The requirement is still deemed proper and is therefore made FINAL.

Claims 4-224 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-224 are pending. Claims 1-3 are examined on merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "MGFR" but it is not clear what the metes and bounds are. Review of the specification indicates that term could be MUC1 Growth Factor Receptor as disclosed "[0056] The term "MUC1 Growth Factor Receptor" (MGFR) is a functional definition meaning that portion of the MUC1 receptor that interacts with an activating ligand, such as a growth factor, to promote cell proliferation. The MGFR region of MUC1 is that portion that is closest to the cell surface and is defined by most or all of the PSMGFR. The MGFR is inclusive of both unmodified peptides and peptides that have undergone enzyme modifications, such as, for example, phosphorylation, glycosylation, etc. Results of the invention are consistent with a mechanism in which this portion is made accessible to the ligand upon MUC1 cleavage at a site associated with tumorigenesis that causes release of the IBR from the cell."

It could mean the amino acid sequence "PSMGFR" as disclosed at:

[0048] FIG. 14 (color) is an image of a 96-well plate illustrating a color-change drug-screening assay identifying several compounds that intefere with the interaction of the MGFR portion of the MUC1 receptor and a multimerizing ligand(s).

[0044] FIG. 10 (color) is a silver-stained gel showing ligands that were fished out of cell lysates using the PSMGFR peptide, in the absence of the protease inhibitor PMSF.

It could also mean the peptide sequence MGFR. If that is the case, then it requires SEQ ID NO because it has four unmodified amino acids.

In addition, "MUC1 Growth Factor Receptor" is not an art-accepted term. It is not clear what "MUC1 Growth Factor Receptor" is. No one in the art has been used the

term except the instant inventors. Note the attached Exhibit A, which is searching the term in Medline through Dialog (155), and 26 other medicine files of Dialog.

For the purpose of this office action, the Office would assume the term means "MUC1 Growth Factor Receptor" as defined at Paragraph [0056], and also means MUC1. However, this treatment does not relieve applicant the burden of responding to this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,108,933 A (April 28, 1992, hereinafter the '933 patent).

Claims 1 and 2 are drawn to a kit comprising a first article comprising a receptor peptide immobilized, and a candidate drug, and further comprising a second article.

The '933 patent teaches at column 7 lines 37 to 52 teach a receptor immobilized to a colloidal agglomerate and an antibody or other substance binding to the receptor.

The '933 patent also teach at column 12 lines 17-34 "magnetic particles, such as specific antibody. Similarly, the well-studied interaction of biotin with avidin may be used to advantage for purposes of causing specific agglomeration reactions where such agents are not otherwise participating in the method. Under such conditions, the resulting agglomerate may be removed from solution via centrifugation, filtration or,

preferably via magnetic separation. It is also possible to use the above-described non-specific and/or specific agglomerating agents in various combinations, if desired. Thus, second colloid addition plus salting out would be feasible, as would the use of a second magnetically responsive colloidal particle bearing a receptor capable of cross-linking with a substance present on the colloidal protein magnetite initially added to the test sample."

Since the method claims in the '933 patent uses the receptor capable of binding to the determinant (see claim 41), it is inherent that the receptor immobilized in the '933 patent is "free of interchain binding region to the extent necessary to prevent spontaneous binding between portion".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over the '993 patent as applied to claims 1 and 2 above, and further in view of Spicer et al., (IDS C2, J. Biol. Chem. Vol. 266, pages 15099-15109).

Claim 3 is drawn to kit comprising a candidate drug and MUC1 protein immobilized to colloidal particle.

See above 102(b) rejection for what the '993 patent teaches. The '993 patent does not teach MUC1 as a receptor being used in a kit.

However, Spice et al., teach that MUC1 has been well known before the effective filing date of the instant application as tumor-associated protein.

Therefore, it would have been obvious to one of ordinary skill in the art to use MUC1 in a kit to screen a useful compound to affect the function of MUC1. Making and using the kit would have been accomplished with a reasonable expectation of success since the immobilization technique and MUC1 sequence had been well known in the art before the effective filing date of the instant application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642